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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/800,256	ZAKAY-RONES ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,24-30,46-52,55-65* is/are pending in the application.

4a) Of the above claim(s) *6-14 and 55-65* is/are withdrawn from consideration.

5)☒ Claim(s) *1* is/are allowed.

6)☒ Claim(s) *2-5,24-30,46-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Final Rejection

Claims 1-14, 24-30, 46-52, and 55-65 are pending.

Applicant's traversal and the amendment to the claims 2, 4, 14, 28,46, 50, 51, 52, 55, and 65 filed on 1/18/06 is acknowledged and considered by the examiner.

Election/Restrictions

Claims 6-14 and 55-65 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/14/05.

Applicant asserts that the examiner incorrectly notes that the election dated 9/14/05 was made without traverse. See page 8 of the response dated 9/14/05 where the election was made with traverse.

However, the examiner acknowledged the election of traverse and the applicant did not provide any arguments with the traversal. Thus, election was treated without traverse. See MPEP § 818.03(a).

Claims 55-65 were directed to a process of making a polypeptide, however, claims 55-65 were amended. The claims are directed to an invention that is still independent or distinct from the invention originally claimed for the following reasons: claims 55-65 are now directed to a process of making a cancer treatment composition comprising an isolated polynucleotide of a replication-deficient NDV. Claims 55-65 directed to a process of making and the product in claims 2-5 are related as process of

making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product in claims 2-5 can be made using another materially different process and would it be an undue burden on the examine to search the process of making and the product.

The process of making in claims 55-65 and the process of using in claims 24-30 and 46-52 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are unrelated because each process has a different mode of operation and different design. The specification does not disclose that the inventions are capable of use together. The search for both set of claims are not coextensive.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims wills be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 55-65 remain withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

Claims 46 and 52 are objected to because of the following informalities: the phrase "at least polypeptide of NDV an analog or subunit thereof having oncolytic activity" is grammatically improper. Appropriate correction is required.

Suggest inserting the term -- or -- after the word NDV.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-5, 24-30, and 46-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New Matter rejection:

The limitation 'replication deficient NDV' in claims 2, 46, and 50 and claims dependent therefrom is not supported by the as-filed specification. Applicant has cited pages 5, 18-20 and 26 for where the limitation in the claims is supposedly supported, however, there does not appear to be a written description of the claim limitation in the application as filed. See MPEP § 2163.06. Page 5 does not disclose a replication deficient NDV. Pages 18-20 disclose the nucleotide sequence of the F and HN genes of HUJ strain of NDV and do not support the limitation. Page 26 discloses that HUJ does

not replicate efficiently in culture without trypsin. However, the skilled artisan understands that HUJ replicate in areas with trypsin-like enzymes (US 6,719,979, column 3). Thus, the HUJ strain disclosed on page 26 is not replication deficient because the virus still replicates in media without trypsin just not as efficiently as in culture with trypsin.

The limitation 'composition comprises a lentogenic oncolytic strain of NDV' in claim 27 and claims dependent therefrom is not supported by the as-filed specification. Applicant has not cited support for where the limitation in the claims is supposedly supported. There does not appear to be a written description of the claim limitation in the application as filed. See MPEP § 2163.06. The amended claim not reads on a method comprising administering a replication defective NDV and a lentogenic oncolytic strain of NDV to a patient. The examiner has thoroughly searched the specification and cannot find support for the limitation.

It is apparent that the applicants at the time the invention was made did not intend or contemplate the limitation recited in the claim and claims dependent therefrom as part of the disclosure of their invention. There is no evidence in the specification that the applicants were in possession of the claimed NDV as set forth in the claims, as it is now claimed, and claims dependent therefrom at the time the application was filed.

Written Description:

Claims 46 and 50 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 46 and 50, as best understood, are readable on a genus of a polynucleotides encoding at least one polypeptide of NDV or an analog or subunit thereof having oncolytic activity, wherein the genus of polynucleotides is not claimed in a specific biochemical or molecular structure that could be envisioned by one skilled in the art at the time the invention was made are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification contemplates a genus of a polynucleotides encoding at least one NDV polypeptide or an analog or subunit thereof having oncolytic activity. The specification provides sufficient description of SEQ ID NO: 1 and the fusion glycoprotein and the hemaglutinin-neuraminidase of NDV. However, the specification only describes NDV and proteins from NDV having oncolytic activity. In view of the term "analog" and "subunit", the genus embraces DNA and RNA viruses that are not disclosed in the instant specification. Other than NDV, the specification does not describe how to make other species embraced by the claimed invention. The specification does not disclose a structure-function correlation between NDV and the claimed genus. Thus, in view of the reasons set forth above and the numerous and complex functions of viral polypeptides, analogs or subunits, the specification does not disclose which activities of NDV correspond to the claimed genus of polynucleotides. It is apparent that on the basis of applicant's disclosure, an adequate written description of the invention defined by the

claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or molecular structures of molecules that are essential for the genus of polynucleotides as claimed; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structures of polynucleotides that must exhibit the disclosed biological functions as contemplated by the claims.

The mere contemplation of a genus of polynucleotides encoding an NDV polypeptide an analog or subunit thereof having oncolytic activity is not sufficient to support the present claimed invention. The claimed invention as a whole is not adequately described if the claims require essential or critical elements, which are not adequately described in the specification and which is not conventional in the art as of applicant's effective filing date. Claiming a genus of polynucleotide sequences that must possess the biological properties as contemplated by applicant's disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of a polynucleotide sequence encoding an NDV polypeptide, analog or subunit thereof that must exhibit the

contemplated biological functions, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Applicant's arguments filed 1/18/06 have been fully considered but they are not persuasive.

In response to applicant's argument that the amendment to the claim to recite "at least one isolated polynucleotide encoding at least one polypeptide of NDV" overcomes the rejection, the argument is not found persuasive because the claims still recites analog and subunit thereof having oncolytic activity. Thus, the rejection remains for the reasons of record.

Claims 4, 5, and 28-30 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention consists of a cloned NDV designated HUJ strain. Claims 4, 5, and 28-30 specifically claim the HUJ strain. Since the HUJ strain is essential to the claimed invention, it must be obtainable be a repeatable method set forth in the specification or otherwise readily available to the

public. If the HUJ strain is not so obtainable or available, the requirements of 35 U.S.C. 112, regarding "how to make", may be satisfied by a deposit of the HUJ strain. It does not appear that the HUJ strain is known and readily available or can be reproducibly made without undue experimentation, and because claims 4, 5, and 28-30 specifically require the HUJ strain. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restriction upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request of the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

This requirement if necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each member State. Amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required.

It is noted that on page 11 of the specification, the applicants deposited HUJ strain with an international reference library and the strain has an assigned reference number. However, the deposit is incomplete because it does not fulfill the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05.

Applicant request that the rejection be held in abeyance. This request does not overcome the rejection of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The term "pharmaceutical composition" in instant claims 2 and 3 does not have patentable weight over the prior art because the term does not distinguish the claimed invention over the prior art. See MPEP 2111-2111.02.

Instant claims 46-52 read on administering a NDV to treat cancer in a patient because NDV comprises a fusion glycoprotein and a hemaglutinin-neuraminidase glycoprotein.

Claims 2, 3, 24-26, and 46-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Groene et al. (US 20030077819). Groene teaches a method of treating a human with cancer comprising administering a pharmaceutical composition comprising NDV having low virulence (lentogenic) and a physiologically acceptable solution (pages 1-2). Groene teaches the virus can be either replication competent or replication incompetent (page 2). Groene teaches the limitation in instant claims 25 and 26 (pages 2-3).

Applicant's arguments filed 1/18/06 have been fully considered and they are persuasive for claims 4 and 28 because of the amendment to the claims.

However, applicant's arguments for claims 2, 3, 24-27 and 46-52 have been fully considered and not found persuasive.

In response to applicant's argument that Groene does not teach using a replication deficient NDV in the method, the argument is not found persuasive because Groene teaches that the NDV can be a lentogenic strain and replication incompetent. See page 2.

In response to applicant's argument that Groene's statement that lentogenic strains are useful goes against the rest of Groene's teaching, the argument is not found persuasive because a reference may be relied upon for all that it would have reasonably

suggested to one having ordinary skill the art, including nonpreferred embodiments. See Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). This is the case here. Groene teaches using a NDV having low virulence (lentogenic strain) wherein the NDV can be replication incompetent. See page 2.

In response to applicant's argument that lentogenic strains certainly do not operate in the same way as the replication competent mesogenic strains, the argument is not found persuasive because Groene teaches that mesogenic strains and lentogenic strains operate differently with respect to their oncolytic activity and both can be used in the method (page 2).

In response to applicant's argument that Groene's statement with respect to lentogenic strains are not enabled and are insufficient to motivate the skilled artisan to utilize replication-deficient lentogenic strains in such compositions or treatment methods, the argument is not found persuasive because "sufficient motivation" to use the virus is not a requirement under 102. See MPEP 2131. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. See In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Furthermore, the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965) and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Other than applicant's assertion that the teaching of Groene is not enabled, applicant has not provided any evidence of record to support applicant's assertion.

In response to applicant's argument that the present invention teaches unexpected finding that the cytopathic effect exerted by a lentogenic strain of NDV does not require efficient viral replication and is not dependent on the production of infectious progeny as required by Groene, the argument is not found persuasive because with respect to the product claims "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." See Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., isolated viral surface glycoproteins) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). This is the case here because the claimed method still reads on using a NDV virus to treat cancer in a patient.

Response to Arguments

Applicant's arguments, see page 8, filed 1/18/06, with respect to 112 second paragraph have been fully considered and are persuasive. The rejection of claims 4, 5, 28, 51 and 52 has been withdrawn because of the amendment to the claims.

Applicant's arguments, see page 8, filed 1/18/06, with respect to 102(e) by Roberts have been fully considered and are persuasive. The rejection of claims 2-5 has been withdrawn because of the amendment to the claim 2.

Applicant's argument, see page 11, filed 1/18/06, with respect to 103(a) over Roberts have been fully considered and are persuasive. The rejection of claims 2-5, 24-30 and 46-52 has been withdrawn because of the amendment to the claims.

Conclusion

Claim 1 is in condition for allowance because SEQ ID NO: 1 is free of the prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-

0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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BRIAN WHITEMAN
PATENT EXAMINER